REMARKS

Status of the Claims

Claims 1, 3-5, 7-9, 11-22 and 30-61 have been canceled without prejudice or disclaimer. Claim 62 has been rewritten in independent form. The term "delivery agent" has been removed from claims 62 and 63. Claims 29 and 62-66 are pending and at issue.

Rejections Under 35 U.S.C. §103

Claims 1, 3-5, 7-9, 11-22, and 29-66 stand rejected as obvious over International Publication No. WO 96/30036.

To advance prosecution, the claims have been amended to call for a pharmaceutical composition including at least about 50% by weight of the disodium salt of *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid ("5-CNAC"), based upon 100% total weight of *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid and salts thereof in the composition. WO 96/30036 does not disclose or suggest *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid, let alone a disodium salt of it. Accordingly, WO 96/30036 does not render obvious the presently claimed invention and this rejection should be withdrawn.

The Examiner also cites International Publication Nos. WO 95/28838 and 97/36480 and U.S. Patent Nos. 4,757,066 and 5,773,647 in the Office Action without providing an explicit rejection over them. In order to be fully responsive, Applicants address these references below.

International Publication No. WO 95/28838 and U.S. Patent No. 4,757,066 alone or in combination, do not disclose or suggest *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid, much less a pharmaceutical composition containing at least 50% of the disodium salt of 5-CNAC.

International Publication No. WO 97/36480 and U.S. Patent No. 5,773,647 do not disclose or suggest a pharmaceutical composition containing at least 50% of the disodium salt of 5-

CNAC. *See* the March 16, 2006 Office Action, p. 2, second paragraph, last sentence (admitting that these references do not specify the disodium salt of 5-CNAC).

Rejections Under 35 U.S.C. §112, first paragraph

Claims 1, 5, 9, 13-22, 29-58 and 64 stand rejected for failing to comply with the written description requirement. The Examiner alleges that there is "no written description and definition" of R^5 being substituted or unsubstituted, or the inclusion of alkylarylene or aryl(C_1-C_{12} alkylene). While applicants respectfully disagree with the Examiner, in order to expedite prosecution, the claims have been limited to a particular compound, 5-CNAC. Accordingly, the rejection with respect to the definition of R^5 is moot.

Claim 29 refers specifically to salmon calcitonin. One of ordinary skill in the art would recognize and understand the structure of "salmon calcitonin." (*Cf.* claim 1 of U.S. Patent No. 7,049,283, attached as Exhibit A). Accordingly, this rejection should be withdrawn with respect to claim 29.

The Examiner also argues:

> The expression "growth hormones, interferons, human recombinant insulin, analogs, vitamins, fragments and so on and so on ....." without i.e. partial or complete structure does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language recited without any correlation does not meet the written description requirement for the expression "growth hormones, interferons, human recombinant insulin and analogs, vitamins, fragments and so on" as one of ordinary skill in the art could not recognize or understand the structure from the mere recitation of the function.

Applicants note that the language objected to with respect to the active agents were present in the claims as originally filed. "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." MPEP § 2163 I.A (emphasis added) (citing *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976); *see also* MPEP § 2163 II.A ("Consequently, rejection of an **original** claim for lack of written description should be rare."). The Examiner has the burden of presenting evidence to show why a person skilled in the art would not recognize the disclosure to provide an adequate written description to support the claims.

Here, the Examiner only states that one of ordinary skill would not understand the structure from the mere recitation of the function. Applicants respectfully disagree that the recited terms do not convey to a person of ordinary skill in the art that applicants had possession of the invention.

Initially, applicants note that "[t]here is nothing inherently wrong with defining some part of an invention in functional terms." Functional language does not in and of itself render a claim improper. MPEP §2173.05(g), *citing*, *In re Swinehart*, 439 F.2d 210 (CCPA 1971).

The specific terms referenced by the Examiner -- "growth hormones," "interferons," "human recombinant insulin," and "vitamins" -- refer to well known classes of active agents which would be immediately recognizable to persons of ordinary skill in the art. For example, the term "growth hormones" refers to a peptide hormone that, in humans, is produced by the anterior pituitary. *See* Basic & Clinical Pharmacology, 9th Edition, pages 608-610, attached as Exhibit B. Growth hormones may also be obtained via recombinant technology, or from cows and pigs. See specification as-filed, page 7, lines 16-18 (growth hormones include "human growth hormones (hGH), recombinant human growth hormones (rhGH), bovine growth hormones, and porcine growth hormones").

The term "vitamin" is also well known to persons of ordinary skill and includes active agents that are conducive for normal growth and activity of the body. The terms "analogs" and "fragments" are commonly used, and would therefore also be known and understood by one of

ordinary skill in the art at the time the application was filed. The term "analog" refers to a structural derivative of a parent compound, differing slightly in composition yet having similar activity. *See* the definition of "analog" in Merriam-Webster's Medical Dictionary (2002), Merriam-Webster Inc. The term "fragment" refers to a compound that is a portion of a parent compound having similar activity. Use of these well-known terms do not violate the written description requirement. See MPEP §2163.II.A.3(a), *citing*, *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("what is conventional or well known in the art need not be disclosed in detail"). For the foregoing reasons, applicants request that the rejection be withdrawn.

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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